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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,607	03/26/2001	Fei Yang	DEX-0201	7851

26259 7590 03/20/2003

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>		<b>Applicant(s)</b>	
	09/817,607		FEI YANG	
	<b>Examiner</b>		<b>Art Unit</b>	
	Alana M. Harris, Ph.D.		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1, 3-6 and 9 are pending.

Claims 2, 7, 8 and 10-25 have been cancelled.

Claims 1, 5-6 and 9 have been amended.

Claims 1, 3-6 and 9 are examined to the extent they read on SEQ ID NO: 8, a polynucleotide.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. The information disclosure statement filed September 24, 2001, Paper No. 5 lists a number of documents that were to be considered by the Examiner. The Examiner appreciates Applicants' submission of IDS references AD and AF for consideration. At this point in prosecution the documents that continue not to accompany the instant application for review are references AB, AN and AP. The Examiner attempted to locate these references via interlibrary loan, however at the time of this office action they were not available.

Applicants set forth that the listed "...references are standard reference texts ...known to those of skill in the art" and that "[i]t is the Applicants' belief that the US Patent Office has access to these standard reference texts..". The USPTO is obliged to

accessing US Patents, as well as WO documents. Any other documents considered relevant by Applicants should be submitted for consideration. The listed documents "lined through" were not reviewed during examination and not considered. In order to expedite prosecution it is requested that these references be supplied for consideration.

### ***Claim Objections***

4. Claim 1 continues to be objected because of the following informality: it contains reference to non-elected inventions. Correction is required.

### ***Withdrawn Rejection***

#### ***Claim Rejections - 35 USC § 112***

5. The rejection of claims 1, 3-6 and 9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of Applicants' arguments and declaration by Dr. Roberto Macina submitted January 13, 2003.

6. The rejection of claims 5, 6 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment to claims 5, 6 and 9.

***Maintained Rejection***

***Claim Rejections - 35 USC § 112***

7. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicants argue that the “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of : [three criteria]” and “the specification at page 18 teaches that by stringent conditions it is meant that hybridization will occur only if there is at least 95%, and more preferably at least 97% identity between the sequences.” These arguments have been carefully considered but found unpersuasive.

The Examiner has reviewed the specification has not found the guidance or teachings that explicitly disclose the conditions defining the recitation, “hybridizing under stringent conditions”. Applicants have yet to pointedly express where within *their* disclosure the recitation “hybridizing under stringent conditions” is defined and the conditions encompassed the recitation. Page 18 of the specification does not forth conditions or the necessary criteria to implement the claimed invention. Absent clear and definite limitations regarding the stringency conditions the metes and bounds continue to be unclear.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

8. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 8, a colon specific gene (CSG) and not a polynucleotide comprising a fragment of at least 15 contiguous nucleobases of SEQ ID NO: 8 and the vector and host cell containing these polynucleotides and a method for producing the encoded polypeptide, which are to be implemented in Applicants' methods.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by

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structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants broadly claim polynucleotides comprising 15 contiguous nucleobases of SEQ ID NO: 8, wherein the nucleic acids encompassing the said nucleobases are not of record in the disclosure. These undisclosed polynucleotides are allegedly efficient in colon cancer diagnostic methods. However, Applicant is not entitled, nor is the specification enabled for the use of this infinite number of polynucleotides that comprise an undefined 15 contiguous fragment of SEQ ID NO: 8, which may or may not be effective as a breast cancer marker. Applicant is not permitted to claim all polynucleotides that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. There is no disclosure of any other CSG comprising 15 contiguous nucleobases beyond the mention of the examined SEQ ID NO: 8 made in the specification. There is no description of which particular 15 contiguous nucleobases of SEQ ID NO: 8 should be comprised within an undefined polynucleotide, no information on the polynucleotides comprising the contiguous nucleobases and no information regarding the relation of the encoded protein's structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

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9. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' claims encompass an isolated polynucleotide (SEQ ID NO: 8), as well as undefined polynucleotides comprising fragments of SEQ ID NO: 8 that more than likely will not encode the same protein encoded by SEQ ID NO: 8 (also known as Clone Id clnc00000827). The said claims also include a polynucleotide which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 8 contained within a vector and host cell, a method for producing said polynucleotide, regarded as a CSG molecule and using the said molecule for diagnoses of colon cancer. Furthermore, the claims also include the nucleic acid sequence, which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 8.

Applicants' specification, as well as the submitted declaration evidence the diagnostic applicability of SEQ ID NO: 8. However, neither the specification nor declaration provide support for the use of polynucleotides comprising arbitrary 15 contiguous nucleobases of SEQ ID NO: 8. On pages 57 and 58 the application provides Tables 4-6, which show levels of expression of sqcln017 (also known as SEQ ID NO: 8 or Clone Id clnc00000827) in numerous samples including normal samples and colon cancer samples. And Dr. Macina's declaration asserts that the indication of the level of colon tissue specific expression of the sqcln017 is higher compared to all the other tissue types tested. None of these tables exemplify the discriminate detection



of colon cancer with polynucleotides other than SEQ ID NO: 8 (sqcln017). The specification does not enable one of ordinary skill in the art to definitively assess the incidence of colon cancer with polynucleotides other than SEQ ID NO: 8. There is insufficient evidence provided to support the use of the undescribed sequences in a diagnostic method for colon cancer. There is no disclosure designating what changes to the coding sequences could be tolerated enabling one of ordinary skill in the art to make and use the said sequences in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of polynucleotide sequences other than SEQ ID NO: 8 in diagnostic methods relative to colon cancer. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988). This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein.

Applicants have not set forth any supporting evidence that suggests that polynucleotides other than SEQ ID NO: 8 is a unique tumor or molecular marker for colon cancer.

Additionally any polynucleotide sequence that binds to the antisense SEQ ID NO:8 would not necessarily be useful as a colon specific gene for diagnosing colon cancer. Furthermore, this bound polynucleotide contained within a vector and host cell may not produce a colon specific gene useful for the methods within the specification.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals 1991 Catalog, page 557. The catalog discloses random primers that are hexanucleotides containing all possible 6-nucleotide sequences that would hybridize under stringent conditions to an antisense sequence of SEQ ID NO: 8.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-

0196.

ALANA HARRIS  
PATENT EXAMINER



Alana M. Harris, Ph.D.  
March 20, 2003